



WEST VIRGINIA SECRETARY OF STATE

KRIS WARNER

ADMINISTRATIVE LAW DIVISION

eFILED

4/13/2026 1:29:25 PM

Office of West Virginia
Secretary Of State

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: Health TITLE-SERIES: 64-57
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: CLINICAL LABORATORY PRACTITIONER
LICENSURE

CITE STATUTORY AUTHORITY: W. Va. Code §16-1-4, §16-1-11, and §16-5J-10

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) HB4215

Section §64-5-1 Passed On 2/27/2026 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

July 1, 2026

This rule shall terminate and have no further force or effect from the following date:

August 01, 2031

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Virginia M Payne -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 64
LEGISLATIVE RULE
DEPARTMENT OF HEALTH
BUREAU FOR PUBLIC HEALTH

SERIES 57
CLINICAL LABORATORY PRACTITIONER LICENSURE

§64-57-1. General.

1.1. Scope. -- This legislative rule sets forth standards and procedures for the licensing of clinical laboratory practitioners and establishes penalties for the use of unlicensed persons to perform the work of clinical laboratory practitioners by healthcare facilities.

1.2. Authority. -- W. Va. Code §16-1-4, §16-1-11, and §16-5J-10.

1.3. Filing Date. -- April 13, 2026.

1.4. Effective Date. -- July 1, 2026.

1.5 Sunset Provision. -- This rule shall terminate and have no further force or effect on August 1, 2031.

1.6. Applicability. -- Except as otherwise provided in this rule, this rule applies to:

1.6.1. Clinical laboratory practitioners who perform moderate or high complexity clinical laboratory tests as categorized pursuant to the criteria established in 42 CFR 493.17 of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and

1.6.2. Clinical laboratory consultants, directors, supervisors, or testing personnel not otherwise excluded in subsection 1.6.3. who perform moderate or high complexity testing or manipulate and report data obtained from laboratories in West Virginia.

1.6.3. This rule does not apply to:

1.6.3.a. Any individual who performs only laboratory tests categorized as waived under the criteria set forth in 42 CFR 493.15 and approved by the FDA pursuant to 42 U.S.C. §263a for use in a waived setting;

1.6.3.b. Any physician, dentist, nurse practitioner, nurse midwife, or physician assistant, licensed within this state who performs only provider-performed microscopy procedures within the scope of his or her professional license and training pursuant to 42 CFR 493.19;

1.6.3.c. Any respiratory care provider licensed within the state who performs moderate complexity blood gas and/or hemoximetry testing within the scope of his or her professional license and training as follows:

1.6.3.c.1. Blood gases are limited to pH, pCO₂, pO₂, and sO₂;

1.6.3.c.2. Oximetry is limited to total hemoglobin, hemoglobin fractions, and hematocrit;

1.6.3.c.3. Potassium, chloride, sodium, ionized calcium, glucose, and lactate; and

1.6.3.c.4. Calculations derived from the listed tests may be reported.

1.6.3.d. An individual who performs laboratory tests only on himself or herself or members of his or her family;

1.6.3.e. An individual employed as a clinical laboratory practitioner in an agency or organization exempt from licensure or CLIA certification in accordance with 42 CFR 493.3;

1.6.3.f. A medical doctor, doctor of osteopathy, or doctor of podiatry licensed to practice medicine, osteopathy, or podiatry in West Virginia;

1.6.3.g. A doctor of philosophy performing laboratory testing within the scope of his or her degree and board certification;

1.6.3.h. A clinical laboratory consultant, director, or supervisor who is not otherwise subject to one of the exceptions set forth in subsection 1.6.3. and does not perform moderate to high complexity testing or manipulate and report data obtained from laboratories in the state; and

1.6.3.i. An individual who strictly performs specimen collection, preparation, or processing but does not perform tests. These procedures may include, but are not limited to, accessioning aliquoting specimens into secondary containers and embedding, cutting, and staining paraffin block samples.

1.6.4. Laboratories that employ exempt testing personnel are directly responsible for verifying that the individual's education, certification, and experience meet the minimum CLIA requirements for testing personnel set forth in 42 CFR 493.1423 and 42 CFR 493.1489, and maintaining documentation for inspection purposes. Laboratories must also maintain qualification documents for licensed individuals for inspection purposes.

1.6.5. A pharmacist with a PharmD licensed to practice in West Virginia practicing within the scope of their professional license.

1.7. Prohibition -- No person may perform any duty of a licensed clinical laboratory practitioner in the state, except where exempted in subsection 1.6.3., unless he or she is licensed by the Secretary as a clinical laboratory practitioner.

1.8. Enforcement. -- This rule is enforced by the Secretary of the West Virginia Department of Health.

§64-57-2. Definitions.

2.1. Certifying agency -- Certifying agency means one of the following institutions:

2.1.1. American Society for Clinical Pathology (ASCP);

- 2.1.2. American Medical Technologists (AMT);
- 2.1.3. American Association of Bioanalysts (AAB);
- 2.1.4. American Board of Bioanalysts (ABB);
- 2.1.5. American Board of Clinical Chemistry (ABCC);
- 2.1.6. American Board of Forensic Toxicology (ABFT);
- 2.1.7. American Board of Medical Genetics and Genomics (ABMGG);
- 2.1.8. American Board of Medical Laboratory Immunology (ABMLI);
- 2.1.9. American Board of Medical Microbiology (ABMM);
- 2.1.10. American College of Histocompatibility and Immunogenetics (ACHI); and
- 2.1.11. National Registry of Certified Chemists (NRCC).

2.2. CLIA. -- Clinical Laboratory Improvement Amendments of 1988, Section 353 of the Public Health Service Act, 42 CFR Part 493.

2.3. Clinical Laboratory. -- A facility certified by CLIA to perform clinical testing for the purpose of determining, measuring, or otherwise describing the presence or absence of various substances or organisms in the body for the diagnosis, prevention or treatment of any disease, or the impairment of, or the assessment of the health of human beings.

2.4. Clinical Laboratory Consultant. -- A person who meets the qualifications for:

- 2.4.1. Moderate complexity testing technical consultant found at 42 CFR 493.1411;
- 2.4.2. Moderate complexity testing clinical consultant found at 42 CFR 493.1417; or
- 2.4.3. High complexity testing clinical consultant found at 42 CFR 493.1455.

2.5. Clinical Laboratory Director. -- A person who:

- 2.5.1._ Provides overall management and direction of a clinical laboratory; and
- 2.5.2._ Meets the qualifications for:
 - 2.5.2.a. Moderate complexity testing laboratory director found at 42 CFR 493.1405; or
 - 2.5.2.b. High complexity testing laboratory director found at 42 CFR 493.1443.

2.6. Clinical Laboratory Practitioner. -- Includes high complexity testing personnel, point of care technicians, cytotechnologists, histologists, pathologist assistants, and trainees.

2.7. Clinical Laboratory Supervisor. -- A person who meets the qualifications for:

2.7.1. A high complexity testing technical supervisor found at 42 CFR 493.1449;

2.7.2. A high complexity testing general supervisor found at 42 CFR 493.1461; or

2.7.3. A high complexity testing cytology general supervisor found at 42 CFR 493.1469.

2.8. Commission on Accreditation of Allied Health Programs (CAAHEP) -- The accrediting organization for cytology educational programs, recognized by the Council for Higher Education Accreditation.

2.9. Cytotechnologist (CT). -- A laboratory practitioner meeting CLIA requirements set forth in 42 CFR 493.1483 who performs the responsibilities set forth in 42 CFR 493.1485, which include examining and interpreting cytology slide preparations under the supervision of a cytology technical or general supervisor and documenting the number of slides reviewed and hours spent examining slides in each 24-hour period.

2.10. Department. -- The West Virginia Department of Health.

2.11. Grossing. -- The pathological inspection, description, measurement, sectioning, and evaluation of human tissue specimens.

2.12. High Complexity Testing Personnel (HCTP). -- A laboratory practitioner meeting CLIA requirements set forth in 42 CFR 493.1489 who performs the responsibilities set forth in 42 CFR 493.1495, which include a broad range of high complexity tests and other tasks requiring the exercise of judgment and responsibility, commensurate with the individual's education, training, or experience in a clinical laboratory.

2.13. Histologist (H) -- A laboratory practitioner with the education, skills, and training to perform high complexity pathology specimen grossing, inking, and mapping, and associated special staining procedures or tissue analysis under the direct supervision of a pathologist or pathologist assistant.

2.14. Laboratory Test. -- The clinical examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

2.15. National Accrediting Agency for Clinical Laboratory Science (NAACLS) -- The accrediting organization for laboratory science-related educational programs, recognized by the Council for Higher Education Accreditation.

2.16 Pathologist Assistant (PA) -- A practitioner with advanced education and training who performs a variety of pathology tests, including comprehensive macroscopic examination and evaluation (grossing) of surgical pathological specimens, under the supervision of a pathologist.

2.17. Point of Care Technician (POCT). -- A laboratory practitioner meeting CLIA requirements set forth in 42 CFR 493.1423 to perform moderate complexity tests commensurate with the individual's education, training or experience, and technical abilities set forth in 42 CFR 493.1425 in a clinical laboratory under the supervision of a clinical laboratory director, consultant, or supervisor. Supervision shall be available at all times when testing is being performed.

2.18. Trainee (T) -- An individual who has obtained appropriate education to perform high-complexity laboratory testing but lacks the required certification and/or experience for a regular HCTP license. Trainees may only perform tests under the personal supervision of a clinical laboratory director, consultant, or supervisor. Supervision must be available at all times when testing is being performed.

§64-57-3. Incorporation by Reference.

3.1. The following provisions of 42 CFR Part 493, laboratory requirements November 28, 2024 are hereby incorporated by reference:

3.1.1. 42 CFR 493.3;

3.1.2. 42 CFR 493.17;

3.1.3. 42 CFR 493.19;

3.1.4. 42 CFR 493.1405;

3.1.5. 42 CFR 493.1411;

3.1.6. 42 CFR 493.1417;

3.1.7. 42 CFR 493.1423;

3.1.8. 42 CFR 493.1425;

3.1.9. 42 CFR 493.1443;

3.1.10. 42 CFR 493.1449;

3.1.11. 42 CFR 493.1455;

3.1.12. 42 CFR 493.1461;

3.1.13. 42 CFR 493.1469;

3.1.14. 42 CFR 493.1483;

3.1.15. 42 CFR 493.1485;

3.1.16. 42 CFR 493.1489; and

3.1.17. 42 CFR 493.1495.

§64-57-4. Limitation.

4.1. A license shall only be issued to an individual currently residing in the United States unless he or she can provide documentation of sponsorship and a valid contract to perform laboratory testing at a facility in the state. Licenses will be issues directly to the sponsoring agency or employer.

4.2. Students in a clinical laboratory training program must obtain a T license before beginning clinical rotations within the State.

4.3. Individuals may not obtain clinical training, perform laboratory tests, or report results until the appropriate license is obtained.

§64-57-5. Documentation, Qualifications, Renewal, License Duration, and Fees.

5.1. General. -- Applicants for licensure under this rule shall submit an application form available online at <https://dhhr.wv.gov/ols/regulatory/Pages/Licensure.aspx> and the following materials:

5.1.1. Initial applications shall include documentation of the applicant's credentials applicable to the license type as outlined in this section.

5.1.1.a. All initial applications shall be accompanied by documentation of education obtained. If the relevant education was obtained in a post-secondary setting, a transcript is required.

5.1.1.a.1. If the relevant education was obtained outside of the United States, the applicant shall provide documentation that each course and degree was verified for equivalency by a foreign equivalency evaluation service.

5.1.1.b. Documentation of training and experience received shall be provided by the method determined by the Secretary at the time of application.

5.1.1.c. All documentation relating to education, training, and experience shall identify the applicant and the issuing entity.

5.1.2. The annual license fee of \$25 per person as authorized by W. Va. Code §16-5J-10 and any other special circumstance fees as required by subsection 5.10.

5.2. Upon initial application for a HCTP license, the applicant shall provide documentation to establish that he or she qualifies via one of the following routes:

5.2.1. Has earned an associates, bachelors, masters, or doctoral degree, or completed post-baccalaureate training in laboratory technology/science at a National Accrediting Agency for Clinical Laboratory Science (NAACLS) accredited program, or has earned a bachelors, masters, or doctoral degree, or equivalent as defined by CLIA, in a chemical or biological science from an accredited institution; and

5.2.1.a. Has obtained certification from a certifying agency identified in subsection 2.1 of this rule; or

5.2.1.b. Has obtained at least one year of documented training and/or experience in a laboratory certified by CLIA to perform high complexity testing that provided the skills necessary to accurately perform testing. A minimum of three months of training or experience must have been obtained within each specialty or subspecialty of testing performed. Training in each specialty may be obtained simultaneously or consecutively.

5.2.2. Has successfully completed 60 semester hours of academic credit at an accredited institution which includes, at a minimum, either 24 semester hours of medical laboratory

technology/medical laboratory science courses or six semester hours of chemistry, six semester hours of biology, and 12 additional semester hours of chemistry, biology, or medical laboratory technology/medical laboratory science, in any combination; and

5.2.3. Has obtained at least one year of documented training and/or experience in a laboratory certified by CLIA to perform high complexity testing that provided the skills necessary to accurately perform testing. A minimum of three months of training and/or experience must have been obtained within each specialty or subspecialty of testing performed. Training in each specialty may be obtained simultaneously or consecutively; or

5.2.4. Has successfully completed an official United States military medical laboratory procedures training course at least 50 weeks in duration and has enlisted in the military as a Medical Laboratory Specialist (Laboratory Technician).

5.3. Upon initial application for a CT license, the applicant must provide documentation to establish that he or she qualifies via one of the following routes:

5.3.1. Has graduated from a school of cytotechnology accredited by the CAAHEP; or

5.3.2. Has obtained certification as a CT from a certifying agency identified in subsection 2.1. of this rule.

5.4. Upon initial application for a PA license, the applicant shall provide documentation to establish that he or she has graduated from a NAACLS accredited pathologist assistant program and obtained certification as a pathologist's assistant from a certifying agency identified in subsection 2.1 of this rule.

5.5. Upon initial application for an H license, the applicant shall provide documentation to establish that he or she qualifies via the following route:

5.5.1. Meets the education requirements set forth in subsection 5.2.1. or subsection 5.2.2. of this rule, at a minimum; and

5.5.1.a. Obtained certification as a histotechnologist or histotechnician from a certifying agency identified in subsection 2.1. of this rule; or

5.5.1.b. Has at least one year of pertinent full-time experience or training in the gross examination of human tissue specimens performed under the supervision of a pathologist.

5.6. Upon initial application for a POCT license, the applicant shall provide documentation to establish that he or she qualifies via the following route:

5.6.1. Has at least a high school diploma or equivalent approved by the state department of education,

5.6.2. Is employed or offered employment in a clinical laboratory certified by CLIA to perform moderate or high-complexity testing; and

5.6.3. Has written verification from the laboratory director or designee that the applicant will receive training designed to provide the skills required by CLIA with respect to the specific moderate complexity tests he or she will perform.

5.6.4. In the event that a POCT licensee performs tests in addition to those that he or she was initially trained to perform, the employer shall provide documentation of the relevant additional training.

5.7. Upon initial application for a T license, the applicant shall provide documentation to establish that he or she qualifies via one of the following routes:

5.7.1. Is employed or offered employment in a clinical laboratory certified by CLIA to perform high complexity testing; and

5.7.2. Meets one or more of the education requirements set forth in subsections 5.2.1. or 5.2.2. of this rule; and

5.7.3. Has not met the certification or training requirements listed in subsections 5.2.3., 5.4., and 5.5.1.b. of this rule; or

5.7.4. Is a student attending a NAACLS-accredited laboratory training program.

5.7.5. A T license may be renewed no more than twice and shall be issued at the discretion of the Secretary. A person may not be licensed as a trainee for more than three years.

5.8. An applicant for renewal of either a current or an expired license shall submit a renewal application, licensure fee of \$25, and documentation of at least 10 hours of continuing education commensurate with the level of complexity of testing the individual performs, completed following the issuance of the most recent license. Acceptable continuing educational activities may include, but are not limited to, laboratory seminars, workshops, related college coursework, employer or vendor-provided in-service training, and credit-awarding continuing education courses.

5.8.1. The following activities are not accepted for continuing education:

5.8.1.a. Time spent conducting laboratory inspections as part of a survey team; and

5.8.1.b. Performance of proficiency testing unless continuing education credits are issued by the accrediting organization or proficiency testing provider.

5.9. Duration of License. -- A clinical laboratory practitioner license expires one year after the date it was issued. In the case of a license which has lapsed or been inactive for five years the individual shall comply with the requirements for issuance of an initial license as described in subsection 5.1. of this rule.

5.10. Additional fees are charged for the following:

5.10.1. A mandatory late fee of \$10 for renewal applications that are submitted after the application due date.

5.10.2. An optional fee of \$10 to print and mail a replacement license.

5.10.3. A mandatory fee of \$20 for reinstatement of a lapsed license.

5.10.4. Any fees required for the use of online licensing systems including, but not limited to, convenience fees, transaction fees, and payment processing fees, as set by and paid to the software vendor or financial institution.

5.10.5. An optional “emergency” issuance fee of \$35 to process an application or other request within three business days.

5.10.6 A penalty of \$100 is assessed to any testing personnel identified as not having a valid license during a laboratory inspection, which is a violation of CLIA personnel requirements under 42 CFR 493.1423(a) and 493.1489(a). The penalty must be paid before a license can be issued or renewed.

5.10.7. A fee of \$10 for official licensure source verification.

5.10.8. A fee of \$35 for payments returned due to non-sufficient funds.

§64-57-6. Reciprocity.

6.1. The Secretary may issue a clinical laboratory practitioner license to a person who holds a license or certification from another jurisdiction that has licensure and certification requirements at least as stringent as the requirements of this rule. Applicants for reciprocity shall submit with their initial application the license application fee, all required documentation, and a statement from their licensing or certifying jurisdiction that they are in good standing.

§64-57-7. Limitations on License and Use of Titles by Healthcare Facilities.

7.1. Licensure as a clinical laboratory practitioner does not authorize the person to perform laboratory tests until the CLIA laboratory director has determined that the person is qualified by education, training, or experience required by 42 CFR 493.1423, 42 CFR 493.1483, or 42 CFR 493.1489 to perform such tests.

7.2. Healthcare facilities may not use the terms cytotechnologist, point of care technician, high complexity testing personnel or abbreviations thereof, to refer to a person who is not licensed as a clinical laboratory practitioner. A facility is not prohibited from using the designations, variations, or abbreviations of medical laboratory technician, medical technologist, medical laboratory scientist, pathologist assistant, or histologist to describe, classify, and compensate its employees if the individual holds a valid HCTP license. Each facility is responsible for determining its personnel qualifications, which must be at least as stringent as federal CLIA requirements and this rule.

§64-57-8. Revocation and Non-issuance of Clinical Laboratory Practitioner Licenses.

8.1. A clinical laboratory practitioner license shall not be issued or may be revoked if the applicant for or holder thereof:

8.1.1. Has misrepresented material facts in an application or has assisted another person in doing so;

8.1.2. Does not meet the requirements for licensure; or

8.1.3. Has been found to have intentionally falsified laboratory results or to have engaged in negligent laboratory practices.

8.2. The Secretary may consider reinstatement of a revoked license if the applicant can provide documentation of meeting the requirements of this rule: *Provided*, That no reinstatement is available for a license revoked pursuant to subsections 8.1.1. and 8.1.3.

§64-57-9. Hearings.

9.1. A request for a hearing may be made to the secretary by an applicant for a clinical laboratory practitioner license, by a holder thereof, or by a healthcare facility. The request shall specify the grounds relied upon as a basis for the relief requested.

9.2. Hearings shall be conducted in accordance with the provisions of W. Va. Code § 29A-5-1 *et seq.*, and Bureau's Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64CSR1.